



# ENZYMATIC THERAPY INCORPORATED

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Wilsonville, OR 97070

P: 503.582.8386 ♦ F: 503.582.0467

**ENZYMATIC THERAPY™**  
&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)

P: 920.469.8099 ♦ F: 920.469.4418 (Phyto)

0829 5 MAY -2 13:09

April 13, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	Supports healthy adrenal gland function to help avoid adrenal burnout and fatigue.*	Vitamin C (ascorbic acid and from rose hips), Vitamin B6 (as pyridoxine HCl), Pantothenic Acid (as calcium D-pantothenate), Adrenal Polypeptide Fractions, Betaine, L-Tyrosine, Licorice (Glycyrrhiza glabra) Root and Rhizome Extract, Adrenal Cortex Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/13/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Michael P. Devereux  
Chief Financial Officer

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue Adrenal Stress- End™*	Optimal health is achieved through maintaining balanced hormone levels, that both support the body during stressful events, and promote immune system health.*	Vitamin C (ascorbic acid and from rose hips), Vitamin B6 (as pyridoxine HCl), Pantothenic Acid (as calcium D-pantothenate), Adrenal Polypeptide Fractions, Betaine, L-Tyrosine, Licorice (Glycyrrhiza glabra) Root and Rhizome Extract, Adrenal Cortex Extract

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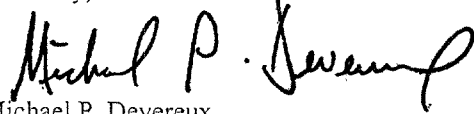
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	Glandulars have been used safely for years to support various functions in the body. For instance, thymus glandular extracts are used for supporting the thymus gland, pancreatic enzymes for actions of the pancreas (digestion, etc.) and of course, adrenal polypeptide and adrenal cortex extracts to help support healthy adrenal gland function.*	Vitamin C (ascorbic acid and from rose hips), Vitamin B6 (as pyridoxine HCl), Pantothenic Acid (as calcium D-pantothenate), Adrenal Polypeptide Fractions, Betaine, L-Tyrosine, Licorice (Glycyrrhiza glabra) Root and Rhizome Extract, Adrenal Cortex Extract

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue Adrenal Stress- End™*	Proteins and polypeptides have been shown to exert effects in target tissues. In addition to thyroid hormone and cortisone, several peptide hormones have been shown to be biologically active when administered orally. Even numerous whole proteins, including plant and animal enzymes, have been shown in human and animal studies to be absorbed intact into the bloodstream following oral administration, to help support many body systems, including thyroid function.*	Vitamin C (ascorbic acid and from rose hips), Vitamin B6 (as pyridoxine HCl), Pantothenic Acid (as calcium D-pantothenate), Adrenal Polypeptide Fractions, Betaine, L-Tyrosine, Licorice (Glycyrrhiza glabra) Root and Rhizome Extract, Adrenal Cortex Extract

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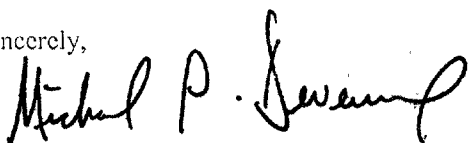
Title: Senior Vice President of Scientific Affairs

Date \_\_\_\_\_

4/14/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is written in a cursive style with a large, stylized "M" and "D".

Michael P. Devereux  
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue Adrenal Stress- End™*	Vitamin C has been shown to help maintain connective tissue and boost the immune system, which may need extra support during periods of chronic stress.*	Vitamin C (ascorbic acid and from rose hips)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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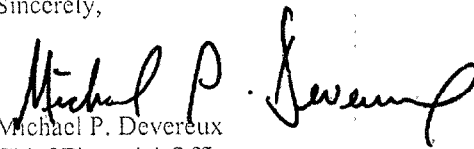
Robert C. Doster

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Date 4/14/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	Vitamin B6 supports the absorption of fats and protein, healthy red blood cell formation, healthy nervous system function and the healthy synthesis of the nucleic acids RNA and DNA, which contain the genetic instructions for the reproduction of all cells and for healthy cellular growth.*	Vitamin B6 (as pyridoxine HCl)

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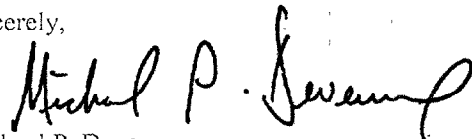
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	Vitamin B6 is required to make serotonin, melatonin and dopamine – all vital in maintaining energy levels.*	Vitamin B6 (as pyridoxine HCl)

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By: 

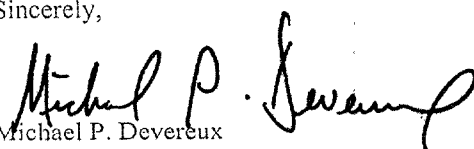
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	Vitamin B6 aids in the formation of several neurotransmitters and therefore is an essential nutrient in the regulation of mental processes and possibly even moods – quite important when dealing with stress-filled lifestyles.*	Vitamin B6 (as pyridoxine HCl)

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By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	Pantothenic acid is an essential component in the production of coenzyme A, a vital catalyst that is required for the conversion of carbohydrates, fats, and protein into energy.*	Pantothenic acid (as calcium D-pantothenate)

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By: 

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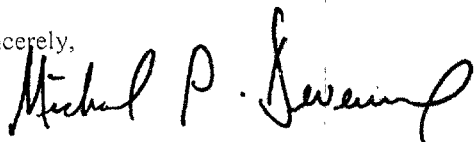
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	Pantothenic acid is necessary in the synthesis of hormones and cholesterol.*	Pantothenic acid (as calcium D-pantothenate)

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Title: Senior Vice President of Scientific Affairs

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	Betaine works with B vitamins to synthesize amino acids, precursor to SAM-e (S-adenosyl-L-Methionine).*	Betaine

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PHYTOPHARMICA™

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P: 920.469.9099 • F: 920.469.4418 (PhytoPharmica)

April 15, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	L-tyrosine (also known simply as "tyrosine") is an amino acid that supports healthy nerve transmission and healthy functioning of the adrenal, thyroid, and pituitary glands.*	L-Tyrosine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

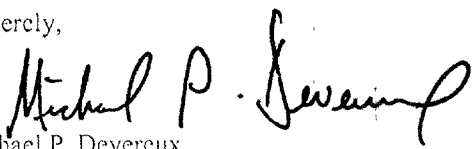
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 4/15/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

  
Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY

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April 15, 2005

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue Adrenal Stress- End™*	Because of its effect on neurotransmitters, L-tyrosine may have an effect on mood and environmental stress.*	L-Tyrosine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 


Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/15/05

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Sincerely,

  
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Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress-End™*	Vitamin B6, included as one of the ingredients in End Fatigue Adrenal Stress-End™ helps convert tyrosine into neurotransmitters.*	Vitamin B6 (as pyridoxine HCl), L-Tyrosine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert C. Doster

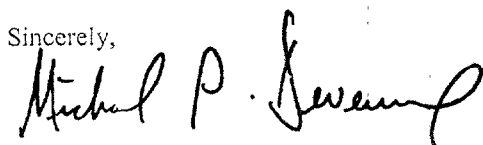
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Date

4/15/05

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Michael P. Devcreux  
Chief Financial Officer



## ENZYMATIC THERAPY

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	One of the most important constituents of licorice is glycyrrhizin, which breaks down into glycyrrhizic or glycyrrhetic acid.* This compound inhibits the breakdown of cortisol produced by the body, helping support a balanced level of this important hormone.*	Licorice (Glycyrrhiza glabra) root and rhizome extract

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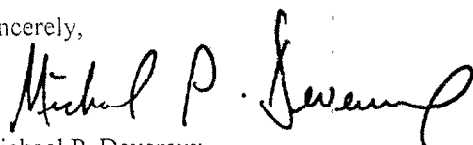
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## ENZYMATIC THERAPY

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
End Fatigue Adrenal Stress- End™*	Glycyrrhizic acid's mechanism of action is through the inhibition of 11- $\beta$ -hydroxysteroid dehydrogenase. This enzyme catalyzes the conversion of cortisol to cortisone. It also inhibits the metabolism of cortisol, and minimizes the binding of cortisol to mineral corticoid receptors.*	Licorice (Glycyrrhiza glabra) root and rhizome extract

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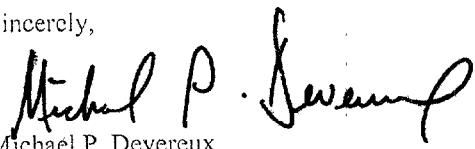
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